



## **ANME`s concrete demand for homeopathic ampoule eu-registration:**

Dear ladies and gentlemen,

the directive 2001.83.EG of the European parliament and the council intends that medicinal homeopathic ampouleproducts fall not under the simplified registration procedure (directive in 2001/83/EG, Art.14.1), but must be registered according to article 8, 10.1 and 11 (summarized in article 16.1).

In these articles it is also referred to the necessary unhurt announcement or application as well as recognized effectiveness and security.

However, this is difficult for Homöopathika which are judged like, unfortunately already so often, our traditional and unproblematic medicinal products are classified by EBM graduations as ineffective. **In reality medicinal homeopathic ampoule products are classified in all EU countries as ineffective, with it neither an advancement nor an innovation takes place (that is no money for the research).**

Germany nationally already has successfully registered medicinal homeopathic ampouleproducts in the market. In addition, some firms decided themselves for the national admittance after § 38 AMG in sence of the directives in article 16.2 .

In case of a rigurosen conversion of the EU directive the medicinal homeopathic ampouleproducts would disappear from the market.

On behalf of users and patients from the EU as well as the manufacturers of medicinal homeopathic ampouleproducts ANME e.V. demands two things.

1. The change of the EU article 14 in the sense that in future all homeopathic medicinal products are defeated by the simplified registration procedures and not only by oral and external application (or alternatively the admission of the parenteral application).

2. Taking into account the article 16.2 of the EU directive the simplified registration can be decided current for all medicinal homeopathic products at nationallevel. The positive national experiences can be transmitted to the Kommission. So it can be worked with it towards the change of the EU directive for the purposes of the first demand.

ANME e.V. please the decision makers to exert themself for both demands at all levels.